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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,393	08/20/2004	Mitsuaki Kuwano	04561/HG	7247

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EXAMINER	
ELLIS, SUEZU Y	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,393	KUWANO ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/04, 11/9/04, 12/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on August 20, 2004, November 9, 2004 and December 17, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The disclosure is objected to because of the following informalities:

It appears throughout the specification, the word "periocularlly" is misspelled. It appears the correct spelling should be "periocularly".

Appropriate correction is required.

Claim Objections

Claim 2 is objected to because of the following informalities:

With respect to claims 1 and 8, it appears the word "periocularlly" is misspelled. It appears the correct spelling should be "periocularly"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The terms "posterior segment" and "disease of a tissue in the posterior segment" are not adequately described to convey what is the posterior segment, what it comprises, what diseases of which tissues affecting which part (or the entire posterior segment), does not adequately describe for one skilled in the art to envision. It is unclear what would be encompassed by the terms as addressed in the 112, 2nd paragraph rejection below. Additionally, claim 14 uses the term "posterior segment of the eye. The specification addresses the posterior segment of the eye, with disclosure of "such as retina, choroid, and optic nerves...", which is not adequate as the term "posterior segment" can be anything in the eye including the fovea, the posterior ciliary artery, the optic disc, the central retinal vein, the sclera. The specification does not provide sufficient descriptive support for the myriad of tissues, organs, and vessels

embraced by the claims. As a result, the specification does not also provide sufficient descriptive support for the myriad of diseases for the number of tissues, organs, and vessels embraced by the claims. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 6, 8-12 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (see MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in

the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of therapy and/or prevention for a disease of a tissue in the posterior segment. For purposes of examination, the claims are viewed as any condition to any structure in the eye. Thus, the claims taken together with the specification imply a method of therapy and/or prevention for a disease of any tissue in the posterior area of the eye.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art as addressed by Newman (Hereditary Optic Neuropathies: From the Mitochondria to the Optic Nerve) and the International Foundation for Optic Nerve Disease (Lever Hereditary Optic Neuropathy) teaches the issues and etiology of hereditary optic neuropathies, specifically Leber's Hereditary Optic Neuropathy (LHON). This is a maternally-inherited disease that results in a permanent loss of central Vision as a result of optic nerve degeneration, rod dystrophy, and abnormal changes of blood vessels in the area. The loss of vision is permanent with no known cure or treatment. As a result, the unpredictability is high as there is no known means of prevention (cure) or treatment for LHON.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for formulating the drug particles, injecting the particles to the eye of rabbits, and the presence of the drug in the eye upon evaluation.

However, the specification does not provide for any method of treatment for any condition or prevention of any condition.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the lack of treatment and prevention of hereditary optic neuropathies, specifically Leber's Hereditary Optic Neuropathy (LHON), and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 2 and 8-12, it is unclear what the "posterior segment" is since this terminology is not defined in the claims, and the term "posterior" is a relative term which is indefinite and there is no point of reference or degree of reference. In the event the "posterior segment" involves the eye, it is unclear what specific structures of

the eye are addressed as it could be the choroid, the retina, the fovea, the posterior ciliary artery, the optic disc, the central retinal vein, the sclera, the vitreous fluid, and many others. Please clarify.

With respect to claims 8-12, it is unclear what the "disease of a tissue in the posterior segment" is since this terminology is not defined in the claims, and the term "posterior" is a relative term which is indefinite and there is no point of reference or degree of reference. In the event the "disease of a tissue in the posterior segment" involves the eye, it is unclear what specific structures of the eye are addressed as it could be the choroid, the retina, the fovea, the posterior ciliary artery, the optic disc, the central retinal vein, the sclera, the vitreous fluid, and many others. As a result, a "disease of a tissue in the posterior segment" when it is unclear what tissues are involved and what the circumstances delineating what the disease state is, renders the claims indefinite.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogura et al. (JP 2000-247871).

With respect to claims 1, 2, 5 and 15, Ogura et al. discloses a periocular injection which comprises fine particles containing a drug and enables the drug to be delivered to a posterior segment (retina) (abstract; [0018]).

With respect to claims 8 and 11, Ogura et al. discloses method of treating and/or preventing a disease of a posterior segment (retina) comprising administering periocularly (injection) to a patient an effective amount for treatment of an injection comprising fine particles containing a drug (abstract; [0012], [0018]).

With respect to claims 3, 13 and 9, Ogura et al. discloses the average particle diameter of the fine particles is 50 nm to 150nm [0021].

With respect to claims 4, 14 and 10, Ogura et al. discloses the fine particles are made of biodegradable polymer [0010].

With respect to claims 6 and 16, Ogura et al. discloses the drug is a drug for treatment of a disease of the retina [0012].

With respect to claims 7, 12 and 17, Ogura et al. discloses drug is an anti-inflammatory [0012], [0014].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-12 and 14 of copending Application No. 10/568,892. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method of therapy and/or prevention for a disease of a posterior segment comprising administering periocularly (injection) to a patient an effective amount for treatment of an injection comprising fine particles containing a drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615